

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/583,927	FUNG ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	STEPHEN RAWLINGS	1643

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 27 May 2011.
2. ☒ The allowed claim(s) is/are 96-101, 104-107, 110-119, 122-127, 129-136, 138-147, 149-151, and 153-155.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. <input type="checkbox"/> Notice of References Cited (PTO-892)	5. <input type="checkbox"/> Notice of Informal Patent Application
2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>20110629</u> .
3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>20110527</u>	7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment
4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance
	9. <input type="checkbox"/> Other _____.

/Stephen L. Rawlings/  
Primary Examiner, Art Unit 1643

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Laura Coruzzi and Hong-Van Le on July 8, 2011.
3. The application has been amended as follows:

In the claims:

The following set of claims has replaced the prior set of claims:

1-95. (Canceled)

96. (Currently Amended) A polynucleotide encoding a heavy chain or a variable heavy chain region of a monoclonal antibody that specifically binds human IL-13, wherein said monoclonal antibody comprises ~~antigen-binding regions derived from an a heavy and light chain variable region comprising the complementarity determining regions of the~~ anti-IL-13 antibody ~~comprising the amino acid sequence of an antibody~~ produced by a hybridoma designated with American Type Culture Collection ("ATCC") accession number PTA-5657.

97. (Currently Amended) A polynucleotide encoding a light chain or a variable light chain region of a monoclonal antibody that specifically binds human IL-13, wherein said monoclonal antibody comprises ~~antigen-binding regions derived from an a heavy and light chain variable region comprising the complementarity determining regions of~~

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~~the~~ anti-IL-13 antibody ~~comprising the amino acid sequence of an antibody~~ produced by a hybridoma designated with American Type Culture Collection ("ATCC") accession number PTA-5657.

98. (Currently Amended) The polynucleotide of claim 96, wherein said monoclonal antibody that specifically binds human IL-13 comprises (i) complementarity determining regions CDRH1, CDRH2 and CDRH3 having the sequences of SEQ ID NO: 117, SEQ ID NO: 123, and SEQ ID NO: 135, respectively; and (ii) complementarity determining regions CDRL 1, CDRL2 and CDRL3 having the sequences of SEQ ID NO: 99, SEQ ID NO: 104, and SEQ ID NO: 115, respectively.

99. (Currently Amended) The polynucleotide of claim 97, wherein said monoclonal antibody that specifically binds human IL-13 comprises (i) complementarity determining regions CDRH1, CDRH2 and CDRH3 having the sequences of SEQ ID NO: 117, SEQ ID NO: 123, and SEQ ID NO: 135, respectively; and (ii) complementarity determining regions CDRL 1, CDRL2 and CDRL3 having the sequences of SEQ ID NO: 99, SEQ ID NO: 104, and SEQ ID NO: 115, respectively.

100. (Currently Amended) The polynucleotide of claim 96, wherein said monoclonal antibody that specifically binds human IL-13 comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 143.

101. (Currently Amended) The polynucleotide of claim 97, wherein said monoclonal antibody that specifically binds human IL-13 comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO: 142.

102 and 103. (Canceled)

104. (Currently Amended) The polynucleotide of claim 96, wherein said monoclonal antibody that specifically binds human IL-13 comprises a heavy chain

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variable region comprising the amino acid sequence of SEQ ID NO: 4, 143, 145, 146, 147, 148 or 149.

105. (Currently Amended) The polynucleotide of claim 97, wherein said monoclonal antibody that specifically binds human IL-13 comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO: 3, 142, 144 or 150.

106. (Currently Amended) The polynucleotide of claim 96 or 98, wherein said monoclonal antibody that specifically binds human IL-13 is a monovalent antibody, a multispecific antibody, a chimeric antibody, a humanized antibody, a single chain antibody, a Fab fragment or a F(ab') fragment.

107. (Currently Amended) The polynucleotide of claim 97 or 99, wherein said monoclonal antibody that specifically binds human IL-13 is a monovalent antibody, a multispecific antibody, a chimeric antibody, a humanized antibody, a single chain antibody, a Fab fragment or a F(ab') fragment.

108 and 109. (Canceled)

110. (Currently Amended) The polynucleotide of claim [[104]] 96, wherein said monoclonal antibody that specifically binds human IL-13 comprises a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 4.

111. (Currently Amended) The polynucleotide of claim [[105]] 97, wherein said monoclonal antibody that specifically binds human IL-13 comprises a light chain variable region comprising the amino acid sequence of SEQ ID NO: 3.

112. (Currently Amended) The polynucleotide of claim 106, wherein the ~~antibody is a multispecific antibody that~~ is a bispecific antibody.

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113. (Currently Amended) The polynucleotide of claim 107, wherein the ~~antibody~~ is a multispecific antibody ~~that~~ is a bispecific antibody.

114. (Currently Amended) The polynucleotide of claim [[106]] 96 or 98, wherein the monoclonal antibody is a humanized antibody.

115. (Currently Amended) The polynucleotide of claim [[107]] 97 or 99, wherein the monoclonal antibody is a humanized antibody.

116. (Currently Amended) A polynucleotide encoding a heavy chain or a variable heavy chain region of a monoclonal antibody that specifically binds human IL-13, wherein said monoclonal antibody is a humanized antibody of an antibody produced by a hybridoma designated with ATCC accession number PTA-5657, wherein said humanized antibody comprises (i) complementarity determining regions CDRH1, CDRH2 and CDRH3 having the sequences of SEQ ID NO: 117, SEQ ID NO: 123, and SEQ ID NO: 135, respectively; and (ii) complementarity determining regions CDRL 1, CDRL2 and CDRL3 having the sequences of SEQ ID NO: 99, SEQ ID NO: 104, and SEQ ID NO: 115, respectively.

117. (Currently Amended) A polynucleotide encoding a light chain or a variable light chain region of a monoclonal antibody that specifically binds human IL-13, wherein said monoclonal antibody is a humanized antibody of an antibody produced by a hybridoma designated with ATCC accession number PTA-5657, wherein said humanized antibody comprises (i) complementarity determining regions CDRH1, CDRH2 and CDRH3 having the sequences of SEQ ID NO: 117, SEQ ID NO: 123, and SEQ ID NO: 135, respectively; and (ii) complementarity determining regions CDRL 1, CDRL2 and CDRL3 having the sequences of SEQ ID NO: 99, SEQ ID NO: 104, and SEQ ID NO: 115, respectively.

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118. (Previously Presented) A polynucleotide encoding a heavy chain or a variable heavy chain region of an antibody that binds human IL-13, wherein said antibody comprises a variable heavy chain region comprising complementarity determining regions CDRH 1, CDRH2 and CDRH3 having the sequences of SEQ ID NO: 117, SEQ ID NO: 123, and SEQ ID NO: 135, respectively; and wherein said antibody comprises a variable light chain region comprising complementarity determining regions CDRL1, CDRL2 and CDRL3 having the sequences of SEQ ID NO: 99, SEQ ID NO: 104, and SEQ ID NO: 115, respectively.

119. (Previously Presented) A polynucleotide encoding a light chain or a variable light chain region of an antibody that binds human IL-13, wherein said antibody comprises a variable heavy chain region comprising complementarity determining regions CDRH1, CDRH2 and CDRH3 having the sequences of SEQ ID NO: 117, SEQ ID NO: 123, and SEQ ID NO: 135, respectively; and wherein said antibody comprises a variable light chain region comprising complementarity determining regions CDRL 1, CDRL2 and CDRL3 having the sequences of SEQ ID NO: 99, SEQ ID NO: 104, and SEQ ID NO: 115, respectively.

120 and 121. (Canceled)

122. (Currently Amended) The polynucleotide of claim 116, wherein the monoclonal antibody that specifically binds human IL-13 comprises a heavy chain and a light chain variable region comprising the amino acid sequence of SEQ ID NO: 143 and SEQ ID NO: 142, respectively.

123. (Currently Amended) The polynucleotide of claim 117, wherein the monoclonal antibody that specifically binds human IL-13 comprises a heavy chain and a light chain variable region comprising the amino acid sequence of SEQ ID NO: 143 and SEQ ID NO: 142, respectively.

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124. (Previously Presented) The polynucleotide of claim 118, wherein the antibody that binds human IL-13 comprises the amino acid sequence of SEQ ID NO: 143 and SEQ ID NO: 142.

125. (Previously Presented) The polynucleotide of claim 119, wherein the antibody that binds human IL-13 comprises the amino acid sequence of SEQ ID NO: 143 and SEQ ID NO: 142.

126. (Currently Amended) The polynucleotide of claim 116[[,]] or 117, ~~120, or 121~~, wherein said monoclonal antibody that specifically binds human IL-13 is selected from the group consisting of: a monovalent antibody, a multispecific antibody, a single chain antibody, a Fab fragment, and a F(ab') fragment.

127. (Currently Amended) The polynucleotide of claim 126, wherein said ~~antibody that binds human IL-13~~ is a multispecific antibody ~~that is a bispecific antibody~~.

128. (Canceled)

129. (Currently Amended) The polynucleotide of claim 118[[,]] or 119, wherein said antibody that binds human IL-13 is a monovalent antibody, a multispecific antibody, a chimeric antibody, a humanized antibody, a single chain antibody, a Fab fragment, or a F(ab') fragment.

130. (Currently Amended) The polynucleotide of claim 129, wherein said ~~antibody that binds human IL-13~~ is a multispecific antibody ~~that is a bispecific antibody~~.

131. (Previously Presented) The polynucleotide of claim 118 or 119, wherein said antibody is a monoclonal antibody.

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132. (Currently Amended) The polynucleotide of claim 116~~[[,]] or 117, 120, or 121~~, wherein the monoclonal antibody is an IgG antibody.

133. (Previously Presented) The polynucleotide of claim 118 or 119, wherein the antibody is an IgG antibody.

134. (Previously Presented) The polynucleotide of claim 132, wherein the antibody is an IgG1, an IgG2, an IgG3 or an IgG4 antibody.

135. (Previously Presented) The polynucleotide of claim 133, wherein the antibody is an IgG1, an IgG2, an IgG3 or an IgG4 antibody.

136. (Currently Amended) The polynucleotide of claim 96, 97, 98, or 99, wherein the monoclonal antibody is an IgG1, an IgG2, an IgG3 or an IgG4 antibody.

137. (Canceled)

138. (Currently Amended) A vector comprising one or more of the ~~polynucleotide~~ polynucleotides of claim claims 116, 117, 118, ~~[[or]]~~ and 119.

139. (Currently Amended) The vector of claim 138, wherein said vector comprises a polynucleotide encoding (i) a heavy chain or a variable heavy chain region, and (ii) a light chain or a variable light chain region~~[[,]]~~ of the antibody that binds human IL-13.

140. (Currently Amended) A host cell comprising one or more ~~vectors of claim 138~~ polynucleotides of claims 116, 117, 118, and 119.

141. (Currently Amended) ~~[[A]] The host cell of claim 140 comprising a vector of claim 139~~ a polynucleotide encoding a variable heavy chain region and a



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polynucleotide encoding a variable light chain region of the antibody that binds human IL-13.

142. (Previously Presented) The host cell of claim 140, wherein the host cell is a mammalian cell.

143. (Previously Presented) The host cell of claim 141, wherein the host cell is a mammalian cell.

144. (Previously Presented) The host cell of claim 142, wherein the mammalian cell is a Chinese hamster ovary (CHO) cell.

145. (Previously Presented) The host cell of claim 143, wherein the mammalian cell is a Chinese hamster ovary (CHO) cell.

146. (Previously Presented) The host cell of claim 140, wherein the host cell is a bacteria.

147. (Previously Presented) The host cell of claim 141, wherein the host cell is a bacteria.

148. (Canceled)

149. (Previously Presented) A method of producing an antibody that binds human IL-13, wherein said method comprises culturing a host cell of claim 141.

150. (Currently Amended) A method of producing an antibody that binds human IL-13, wherein said method comprises culturing a host cell of claim [[142]] 143 that expresses a heavy chain or a variable heavy chain region and a light chain or a variable light chain region of the antibody that binds human IL-13.

151. (Previously Presented) A method of producing an antibody that binds human IL-13, wherein said method comprises culturing a host cell of claim 143.

152. (Canceled)

153. (Currently Amended) The method of claim 149, further comprising the step of obtaining the antibody expressed by the host cell.

154. (Currently Amended) The method of claim 150, further comprising the step of obtaining the antibody expressed by the host cell.

155. (Currently Amended) The method of claim 151, further comprising the step of obtaining the antibody expressed by the host cell.

### ***Conclusion***

4. Claims 96-101, 104-107, 110-119, 122-127, 129-136, 138-147, 149-151, and 153-155 have been allowed.

5. Claims 96-101, 104-107, 110-119, 122-127, 129-136, 138-147, 149-151, and 153-155 have been renumbered as claims 1-50, respectively.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHEN RAWLINGS whose telephone number is (571)272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/  
Primary Examiner, Art Unit 1643

slr  
July 8, 2011